

SEP 29 2008

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GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-QUICKPIN-05
SECTION 5 – QUICKPIN: 510(k) SUMMARY		

INTENDED USE:

QUICKPIN is a Luer-lock spike used in manual or automated pharmacy compounding for addition and/or extraction of IV substances, including antineoplastics and substances for chemotherapy, from rubber-stoppered containers including multi-dose vials.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, QUICKPIN is compared with another vial access device (Chemo-Aide Dispensing Pin – Baxter Healthcare Corporation) and with an IV fluid transfer set previously marketed by Laboratorios Grifols (Fleboset Multiple). The following table summarizes the similarities of the principal technological characteristics and features of both predicate and new devices.

#	Characteristic / Feature	QUICKPIN	PREDICATES	
			BAXTER Chemo Aide Dispensing Pin K003730	LAB.GRIFOLS Fleboset Multiple K040456
1.	Intended use / Claims	QUICKPIN is a Luer-lock spike used in manual or automated pharmacy compounding for addition and/or extraction of IV substances, including antineoplastics and substances for chemotherapy, from rubber-stoppered containers including multi-dose vials.	The Baxter CHEMO-AIDE Dispensing Pin is intended for use in the preparation and dispensing of chemotherapeutic medications from rubber-stoppered vials.	FLEBOSET MULTIPLE is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for: (a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and (b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set. The device should not be used with lipids.

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#	Characteristic / Feature	QUICKPIN	PREDICATES	
			BAXTER Chemo Aide Dispensing Pin K003730	LAB.GRIFOLS Flebozet Multiple K040456
2.	Indications for use	<p>QUICKPIN is a Luer-lock spike used in manual or automated pharmacy compounding for addition and / or extraction of IV substances, including antineoplastics and substances for chemotherapy, from rubber-stoppered containers including multidose vials. It is equipped with a 0.2 micron hydrophobic air-filter that minimizes the formation of aerosols when preparing and dispensing the substances.</p> <p>This device is intended to be used by trained healthcare personnel. It is restricted to sale by or on the order of a physician</p>	The proposed Baxter CHEMO-AIDE Dispensing Pin is intended for use in the preparation and dispensing of chemotherapeutic medications from rubber stoppered vials.	<p>Flebozet multiple is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for:</p> <p>(a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and</p> <p>(b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set.</p> <p>The device should not be used with lipids.</p> <p>This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.</p>
3.	<p>Technological features:</p> <ul style="list-style-type: none"> - Sterilization - Contact with patient 	<p>Ethylene Oxide</p> <p>NO – Intended for use in manual or automated pharmacy compounding of IV substances including</p>	<p>Radiation - Gamma</p> <p>NO – Intended for use by the pharmacist in the preparation and dispensing of chemotherapeutic</p>	<p>Ethylene Oxide</p> <p>YES – May be used on-line with patient, upstream of the gravity administration set or</p>

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SECTION 5 – QUICKPIN: 510(k) SUMMARY		

#	Characteristic / Feature	QUICKPIN	PREDICATES	
			BAXTER Chemo Aide Dispensing Pin K003730	LAB.GRIFOLS Fleboset Multiple K040456
	- Filter	antineoplastics and substances for chemotherapy. YES – 0.2 micron hydrophobic air-filter to minimize the formation of aerosols during preparation and administration of the substances.	medications. YES – 0.22 micron hydrophobic / oleophobic air-venting filter that minimizes potential for aerosolization of chemotherapeutic medications during reconstitution and dispensing process.	infusion pump. YES – 1.2 micron air-venting filter.
4.	Physical, Mechanical and Biological Specifications	Sterile / Non-pyrogenic / Single-use only	Sterile / Non pyrogenic / Single-use only	Sterile / Non pyrogenic Single-use only
5.	Materials	Spike body: ABS (Acrylonitrile butadiene styrene) Luer Protective cap: PP (Polypropylene) Filter housing: PVC Filter: PTFE (Polytetrafluoroethylene)	Spike body: ABS + PE (Acrylonitrile butadiene styrene and polyester) Filter housing: ABS + PE (Acrylonitrile butadiene styrene and polyester) Filter: PVDF (Polyvinylidene fluoride)	Spike body: ABS (Acrylonitrile butadiene styrene) Spikeable twist-off connection: PVC (Polyvinylchloride) Filter housing: PP Filter: Acrylic copolymer + PA
6.	Conformance standards to	The spike conforms to applicable requirements of ISO 8536-4 except regarding spike dimensions which have been adapted specifically for small container access. Materials used meet the requirements of USP physicochemical tests for plastics and biological tests outlined in standard ISO 10993-1.	Materials used meet the requirements of USP physicochemical tests for plastics and biological tests outlined in standard ISO 10993-1.	The spike conforms to applicable requirements of ISO 8536-4. Materials used meet the requirements of USP physicochemical tests for plastics and biological tests outlined in standard ISO 10993-1.

From the above table, it can be established that the new device and the predicate device Baxter Chemo-Aide Dispensing Pin have very similar intended uses and indications. Also, the materials used in the construction of the proposed spike and those used in spike component of the predicate device Fleboset Multiple are identical. Some differences may be noted in the

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dimensions and type of materials used in the filter component and air-inlet on the spike. These differences have been addressed in the different bench tests performed on the proposed QUICKPIN device.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

All materials used in the construction of QUICKPIN have been subject to chemical and biological testing in accordance with the applicable requirements taking account of its intended use.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use.

CONCLUSIONS:

We believe the intended use, the indications for use, the functionality and the operation of QUICKPIN and the CHEMO-AIDE predicate device as access devices for rubber stoppered containers are essentially the same. Also, the materials used in the construction of the proposed device and those used in the spike component of the FLEBOSET MULTIPLE predicate device are identical. Technological differences including the use of different filter materials and different dimensions on the air-inlet channel on the spike have been addressed and verified by bench-testing to have no adverse influence on the safety and performance of the proposed device. Hence, substantial equivalence of QUICKPIN with the legally marketed devices may be established.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2008

Laboratorios Grifols, S.A.
C/O Mr. Norbert Stuibert
Responsible Third Party Officer
TUV SUD America, Incorporated
1775 Old Highway 8 N.W.
New Brighton, Minnesota 55112-1891

Re: K082752

Trade/Device Name: QUICKPIN
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: September 17, 2008
Received: September 19, 2008

Dear Mr. Stuibert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-QUICKPIN-04
SECTION 04 – QUICKPIN: INDICATIONS FOR USE STATEMENT		

**PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT**
 (as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: K082752

Device Name: QUICKPIN

Indications for Use:

QUICKPIN is a Luer-lock spike used in manual or automated pharmacy compounding for addition and / or extraction of IV substances, including antineoplastics and substances for chemotherapy, from rubber-stoppered containers including multidose vials. It is equipped with a 0.2 micron hydrophobic air-filter that minimizes the formation of aerosols when preparing and dispensing the substances.

This device is intended to be used by trained healthcare personnel. It is restricted to sale by or on the order of a physician.

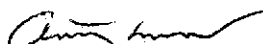
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(21 CFR 801 Subpart D)

OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)


 (Division Sign-Off)
 Division of Anesthesiology, General Hospital
 Infection Control, Dental Devices

510(k) Number: K082752